ISRCTN56877013 https://doi.org/10.1186/ISRCTN56877013

A randomised trial comparing the clinical and cost effectiveness of usual, facility based care compared to an additional collaborative community care package for people and their families living with schizophrenia in India

Submission date
07/10/2009

Recruitment status
No longer recruiting

Registration date
12/10/2009

Overall study status
Completed

Last Edited
24/03/2016

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims.
Community based services for people with schizophrenia are largely lacking in low and middle income country (LAMIC) settings. The lack of accessible care leads to a very large treatment gap and adverse outcomes like continued symptoms, progressive disabilities, high death rates, discrimination and social exclusion. Given the worsening shortage of specialist human resources in these settings, one option of scaling up care is to use lay or non specialist community health workers, working under specialist supervision, deliver additional psychosocial care to a larger number of persons with schizophrenia in the community. Though there is observational evidence in support of community based care from LAMIC, the COPSI trial was designed to compare the clinical- and cost-effectiveness of two service delivery methods for people with moderate to severe schizophrenia across three sites in India.

Who can participate?
Participants aged between 16-60 years with: ii) a primary ICD 10-DCR diagnosis of schizophrenia (ref); iii) illness duration of at least 12 months of at least moderate severity overall as rated by the Clinical Global Impression- Schizophrenia (CGIS) scale; iv) intention to reside in the study areas for 12 months.

What does the study involve?
Individuals who had provided informed consent to participate were randomly allocated to receive either i) a collaborative community based care (CCBC) intervention involving lay community health workers delivering an additional (to ongoing clinical care), structured package of psychosocial interventions under the supervision of specialists or ii) a facility-based care (FBC) intervention delivered only by mental health specialists. The hypothesis was that the CCBC intervention would be superior to FBC alone across a range of outcome measures. The primary outcomes of interest were changes in symptoms and disability over 12 months. The secondary

outcomes of interest were adherence with prescribed medications, stigma and discrimination experienced by participants and their caregivers, family burden and knowledge and attitudes of caregivers.

What are the possible benefits and risks of participating?
By participating in the study, you may experience some benefits that may not happen otherwise. Everyone will have the opportunity to talk to a trained researcher. This can be useful in helping you understand your problems better and to discuss these with your treating doctor. If, by chance, you are in the group being visited by the community health worker, you and your family members might see changes in your life after working with him or her. You could find it upsetting to discuss your experiences of having this illness with someone who you do not know well enough. Our research staff will be well trained to recognize and respond to any such issue. If you feel upset about something and do not wish to continue, you can ask for the interview to stop and be rearranged.

Where is the study run from?
The COPSI study was managed by the Institute of Psychiatry in collaboration with Sangath in Goa, the Schizophrenia Research Foundation in Chennai and Parivartan and Nirmittee at Satara.

When is the study starting and how long is it expected to run for?
May 2008 to December 2012

Who is funding the study?
The Wellcome Trust (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
084355

Study information

Scientific Title
The Community Care for People with Schizophrenia in India (COPSI) Trial: a multi-centre, parallel group randomised controlled trial for evaluating the clinical effectiveness and cost-effectiveness of a collaborative community-based intervention (CCBI) for improving symptoms and social function in people with schizophrenia compared to facility-based care (FBC) in a low income country setting (India), using a parallel group randomised controlled trial design

Acronym
COPSI

Study objectives
Primary hypothesis:
1. That a collaborative community-based intervention (CCBI) involving the treating team, the person with schizophrenia and primary care givers in the family will be superior in reducing the symptoms of people with schizophrenia compared to the usually available, facility-based care (FBC) delivered by one or more mental health personnel, with the primary endpoint at 12 months.

Secondary hypotheses:
Compared with FBC,
2. CCBI will be more effective in reducing the disabilities of people with schizophrenia
3. CCBI will be cost-effective
4. CCBI will be more effective in improving the knowledge and attitudes of family members of people with schizophrenia
5. CCBI will reduce the impact on care givers (family burden)
6. CCBI will improve participants' adherence to treatment
7. CCBI will reduce participants' and care givers' experience of discrimination

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from:
1. Institute of Psychiatry, Kings' College London (UK), 29/07/2009 (ref no: PNM/08/09/121)
2. London School of Hygiene and Tropical Medicine (UK), 26/09/2009 (ref no: 5579)
3. Institutional Review Boards of the Schizophrenia Research Foundation (SCARF) and Sangath (India), 29/06/2009 and 16/09/2008, respectively

Approval from the Indian Council of Medical Research is expected very shortly, pending as of 07/10/2009.

Study design
Parallel group randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details found in the interventions section to request a patient information sheet

Health condition(s) or problem(s) studied
Mental health/schizophrenia

Interventions
For the trial, we will be recruiting participants from three sites in India:
1. In Tamil Nadu, the study will be conducted in four rural blocks or sub-districts: Kattankolathur, Sriperambudur, Kunnuattur and Walaiabad comprising a total of 212 villages with a total population of 716,616 as per the 2001 census (www.censusindia.gov)
2. In Goa, the study will be conducted in collaboration with four psychiatrists in the private sector in both the North and South Districts
3. In Satara, the participants will be recruited from the clinics of four individual psychiatrists working in the private sector
These three sites are diverse and will help strengthen the generalisability of the findings across different social and care settings. These multiple sites will also help ensure that recruitment of participants is feasible within the stipulated time frame of the study.

Collaborative community based intervention (CCBI):
The CCBI is designed to include the person with schizophrenia, the primary care giver(s) and the treatment team working as a collaborative group to provide the intervention in a flexible manner that is matched to needs. The inclusion of treatment components within the treatment package have been guided by:
1. Evidence for the effectiveness of the treatment in LAMIC
2. Whether it is locally feasible, acceptable and potentially of low cost
3. Whether it can be delivered by people with minimal formal health training
4. Whether the services promote access, equity and empowerment of users
The intervention is underpinned by the principles of case management necessary for effective CBI, as has been demonstrated to be effective and feasible in previous work in India.

Delivery of the intervention:
In accordance with the principles of task shifting for the scaling up of health interventions in low income countries with limited human resources, we intend to deliver the CCBI principally through Community Health Workers (CHWs) who are lay persons living in the communities

where the intervention will be implemented. We have carefully selected and trained CHWs from a pool of applicants who have completed at least 10 years of schooling over a period of 6 weeks. The training has been based on the specially designed manual and follows a modular structure with formal, standardised assessments at the end of each module and a final rigorous evaluation to ensure that the CHWs are competent to deliver the intervention. Their responsibilities include provision of treatments, documentation, participation in team meetings and structured supervision sessions.

The CHWs will be supported by Intervention Coordinators (trained Psychiatric Social Workers) who will coordinate the delivery of the intervention and for maintaining the quality standards of the program. The treating Psychiatrists will be the clinical leaders of the community care teams and provide routine clinical care and leadership in ensuring that the safety and quality standards of the intervention is maintained. The caregivers and family members will be encouraged to interact with the treating team members, articulate their perspective and implement the treatments to manage the illness. Self-help and user-led initiatives like groups will also be used to maximize restoration of social roles and to minimize discrimination to the extent possible.

Specific components of the intervention:
The intervention package comprises of a number of individual treatments delivered to participants in accordance with their needs. Thus, there is no uniform, standard package that everyone will get; the choice and the timing of using a particular treatment will depend on a collaborative decision. For each participant, this will be documented and updated in an individualised care plan.

The treatments being offered in the intervention package will include:
1. Information about various issues related to the illness for the participant and the caregivers
2. Adherence management strategies to reduce the rates of non-adherence to treatments
3. Specific efforts to address and reduce the experiences of stigma and discrimination
4. Health promotion strategies to improve the physical health status of people with schizophrenia
5. Specific rehabilitation strategies to improve the personal, social and vocational functioning of participants
6. Linkage to self help groups and other methods of user led support
7. Developing networks with community agencies to facilitate a supportive framework for participants to find employment, and to access the social and legal benefits to which they are entitled in India

Phases of treatment:
There will be three treatment phases during the 12-month intervention:

In the initial, intensive engagement phase, over 3 months, efforts will be made to establish a positive therapeutic alliance with the participant and the caregivers, conduct the needs assessment, develop the individual treatment plan, focus on meeting immediate social needs, provide information to the caregivers and ensure adherence with treatments. This will be delivered by the CHWs in an intensive manner, with face to face meetings once every week to ten days at a convenient location nominated by the participant and care givers.

In the second, stabilisation phase over the next 3 months, the CHWs will meet with the participant every two weeks, consolidate the gains made in the first phase and provide other treatments like information for the participant, reinforce adherence, introduce health promotion, assess the rehabilitation needs and initiate appropriate referral to other community agencies.

In the final, maintenance phase, the CHWs will conduct monthly sessions to reinforce the progress made, discuss strategies to deal with distressing symptoms, discuss specific actions that can be taken to reduce discrimination, focus on restoration of social and economic roles, generate a collaborative relapse prevention plan and address remaining unmet needs, to the extent possible before a carefully planned termination. The overall delivery of the intervention will be guided by the guide in the CHW manual generated for this purpose.

We anticipate that each participant in the CBI arm will receive around 20 planned contacts during the 12 months of the intervention, and that each CHW will carry a maximum case load of 25 people with schizophrenia at any one time.

Facility based treatment (FBC):
At all collaborating sites, treatments are provided from facilities that persons with schizophrenia and their families attend. In most facilities, treatments are provided by a single Psychiatrist; these always include psychotropic medications and sometimes, brief, informal education for participants and caregivers delivered at out-patient clinics. FBC will continue to be available to participants in both study arms.

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Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The change in positive psychotic symptoms in people with schizophrenia measured at baseline and at 12 months, as assessed by the Positive and Negative Syndrome Scale (PANSS) that has been used widely in India before.

Secondary outcome measures
Participants:
1. Change in baseline to 12 month follow-up scores on the locally developed Indian Disability Evaluation and Assessment Scale (IDEAS) which has been used previously in India
2. Cost of Illness Schedule (CIS) for the computing the costs related to the illness; this has been developed and used in India in community studies before
3. Participants adherence to recommended treatment recorded using a specially designed tool that measures adherence from individual, family and treating doctor's assessments
4. Discrimination and Stigma Scale (DISC), a standardised assessment of service user experiences of discrimination because of mental illness that has undergone field trials in India
5. Euroqol (EQ-5D) for estimation of QALYs
6. Internalised Stigma of Mental Illness (ISMI), Alienation Subscale (assessment of internalised stigma)
7. Willingness to disclose - patient version item

Primary caregivers:
1. Burden Assessment Schedule (BAS) which has been developed and widely used in India
2. Knowledge and attitudes of family members using the Knowledge about Schizophrenia Interview (KASI) which has been used in LAMIC settings earlier
3. Family Interview Schedule, (Stigma Section) for the assessment of family perceptions of stigma and discrimination which has been used in India before
4. Willingness to disclose item - caregiver version item

In addition, we will obtain important socio-demographic information about the participant and the primary caregiver at baseline using specially designed forms. All quantitative outcomes using these scales will be assessed at baseline and at 12 months, except for the CIS, adherence scale and the IDEAS which will also be assessed at 6 months - the CIS because recall of service use over a prolonged period may lead to inaccuracies, the adherence scale because of similar problems with recall and the IDEAS as this time period has been found to be feasible in previous studies.

To maintain blinding of these assessments, all outcome measures will be administered by dedicated researchers at the three sites who are independent of the intervention and blind to the allocation of treatment. To enhance blinding, the intervention and research teams at the sites will not have any interactions during the trial with separate physical location and administrative management. In recognition of the fact that neither the treating Psychiatrists or the families will be blind to their allocation status, we will ensure that the researchers are oriented to the notion of clinical equipoise themselves, orient the families prior to each assessment that non-disclosure of whether or not they are receiving home visits from the CHW is necessary and complete the primary outcome measure (PANSS) first. In spite of these precautions, the researcher is unblinded to the allocation status during assessment, the session will be terminated and another researcher will conduct the set of assessments.

Qualitative outcomes:
A proportion of the participants and caregivers recruited for the overall trial will be approached for in-depth-interviews at baseline and at endpoint at 12 months. We intend to recruit 12 participants and 12 primary caregivers (= 12 participantcaregiver dyads) at each site for the in-depth-interviews at baseline. Separate informed consent will be sought for participation in IDIs following the same principles as in the consent procedure for the overall trial described below.

Recruitment for IDIs will only include participants who appear willing and able to communicate at the level required for in-depth-interviews; this information will be recorded by the research staff conducting baseline quantitative assessments and will determine eligibility for the qualitative component of the study.

The same participants and caregivers who are interviewed at baseline will be approached for follow-up interviews 12 months later. In total, therefore, (including all study sites), there will be 36 in-depth-interviews with participants at baseline and 60 interviews or less (depending on attrition) at 12-month-follow-up. The same numbers apply for interviews with caregivers.

In addition, we propose to conduct IDIs with Psychiatrists and community health workers (CHWs) in the program to ascertain:
1. Their satisfaction with work
2. The adequacy of training and supervision
3. Perceptions on the impact of the program
4. Attitudes towards people with mental illness (CHWs)

In addition, key clinical outcomes - inpatient admission (number of episodes and duration of each such episode), relapse (clinically significant exacerbations of symptoms after at least 2 months of well-being), remission (6 months of continued rating of much improved on the CGI-S) and dropout from care (no contact for 4 months or more) will be monitored and recorded for all participants.

Overall study start date
15/10/2009

Completion date
14/08/2011

Eligibility

Key inclusion criteria
Since this is an effectiveness trial, we propose to have broad inclusion criteria that can be generalised to routine, real life settings. Therefore, for inclusion in the trial participants must:
1. Be between the ages of 18 - 60 years, either sex
2. Meet International Classification of Disease, 10th revision, Diagnostic Criteria for Research (ICD-10 DCR) criteria for schizophrenia
3. Have been ill for at least 12 months
4. Be currently having at least an moderate overall severity of the illness based on the Clinical Global Impression-Schizophrenia (CGI-S) scale rating

Two pathways for recruitment are anticipated: people from within the existing caseloads at each of the sites who have ongoing positive symptoms or those who present with a relapse of symptoms; and people who have presented for care for the first time and meet all inclusion criteria irrespective of their treatment status.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
327

Key exclusion criteria
1. The presence of a medical illness needing immediate hospitalisation
2. Participant is unlikely to reside in the identified CBI area for the duration of the study

Date of first enrolment
15/10/2009

Date of final enrolment
14/08/2011

Locations

Countries of recruitment
England

India

United Kingdom

Study participating centre
King's College London
London
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust (grant ref: 084355)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/01/2011		Yes	No
Results article	results	19/04/2014		Yes	No
Results article	results	01/10/2015		Yes	No